Billing code:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS-0990-0260]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795-7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-0260-60D, and project title for reference, to Sherrette Funn, email: Sherrette.Funn@hhs.gov, or call 202-795-7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation.

Type of Collection: Extension

OMB No. 0990-0260 Office of the Assistant Secretary for Health, Office for Human Research Protections

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting a three-year extension of the Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation, OMB No. 0990-0260.

Information reported to the Federal departments and agencies under the Common Rule with respect to a satisfactory assurance is used to ensure that an institution engaged in non-exempt research involving human subjects conducted or supported by a Common Rule department or agency has (1) established adequate administrative policies and procedures for protecting the rights and welfare of human subjects in research, and (2) accepts that responsibility. Other reporting requirements are used to: assess whether the institution is following the established procedures; ensure that Federal funds are not expended for unapproved human subjects research; and, determine if the approved status of an awarded grant, contract, or cooperative agreement should be reviewed, with the ultimate goal of maintaining or increasing human subject protections.

Likely Respondents: institutions, institutional review boards and investigators

Table 1-Estimated Annual Reporting Burden

Common Rule Provision	No. of Respondents	No of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
.103(b)(5), .113 [Pre-2018 Requirements]/.108(a)(4), .113 [2018 Requirements] - Incident	5,200	1	5,200	1	5,200

Reporting, Suspension or Termination of IRB approval Reporting					
TOTAL			5,200		5,200

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Table 2 –Estimated Annual IRB Recordkeeping Burden

Common Rule Provision	No. of Respondents	No of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
.115 [Pre-2018 and 2018 Requirement] – Preparation and documentation of IRB activities	6,000	16	96,000	12	1,152,000
Total			96,000		1,152,000

Table 3 – Estimated Annual Third-Party Disclosure Burden

	No. of Respondents	No of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
.109(d) [Pre-2018 and 2018 Requirements] – Written notification of IRB approval or disapproval of research	6,000	25	150,000	0.5	75,000
.46.116(a) and (b) (Pre-2018	6,000	25	150,000	0.5	75,000

	No. of Respondents	No of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Requirements)/ .46.116 (b), (c) and (d) [2018 Requirements] – Elements of informed consent and broad consent					
.46.116(h) – [2018 Requirements] – Posting clinical trial consent form	100	3	300	0.5	150
.117(a) [Pre-2018 and 2018 Requirements] – Documentation of informed consent	6,000	25	150,000	0.5	75,000
.117(c)(2) [Pre-2018 and 2018 Requirements] – Written statement about the research when informed consent documentation is waived	6,000	10	60,000	1	60,000
TOTAL			510,300		285,150

Sherrrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer,

Office of the Secretary.

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